REMARKS

Upon entry of the foregoing amendment, claims 1-22 are pending for the Examiner's consideration, with claims 1, 14, and 20 being the independent claims. Claim 16 has been amended herein to correct the claim from which it depends. New claims 20-22 have been added. Applicants respectfully submit that the foregoing amendments introduce no new matter, and the Examiner is referred in this regard to the specification and claims as originally filed. Applicants acknowledge with appreciation the allowance of claims 1-13, and the indication of allowability for claims 16 and 17.

Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 14, 15, 18, and 19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,338,931 to Cavazza ("the '931 patent") in view of U.S. Patent No. 6,575,160 to Volgyesi ("the '160 patent"). Applicants respectfully disagree with the rejection made by the Examiner, for at least the reason that there is no motivation to combine the teachings of the foregoing two patents. As such, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness.

The Examiner appears to rely on the embodiment of the '931 patent shown in Figures 6-8, and explained in column 4. In particular, as explained at column 4, lines 28-38 of the '931 patent, "[i]n order to inhale the drug in powder form contained in the capsule, one will operate as described in connection with the first embodiment: the user will place the device end **114A** in his mouth and inhale the powder contained in the capsule by drawing in air through the opposite end **114.** In fact, the drawn in air will enter the capsule through the recess **126**, the hollow needle and the holes **121**, drag in suspension the powder and leave the holes **121A**, the passageway **119A** and the recess **126A** to pass eventually into the user's mouth." However, the Examiner acknowledges that the '931 patent does not teach the step of inhaling at a flow rate less than about 15 L/min as recited in independent claim 14. As such, the Examiner relies on the teachings of the '160 patent.

The Examiner asserts that the '160 patent (column 6, lines 50-60) "teaches a method for dispensing powder by inhaling at a flow rate of 8 L/min in order to sufficiently fluidize the

powder." However, as shown in Figures 3 and 4 of the '160 patent, the inhaler includes a number of holding portions **20** that receive a dose of powdered medicament. As explained in column 6, line 9, through column 7, line 37 of the '160 patent, passageways **22**, each of which includes entry port **24** and exit port **26**, are positioned to direct air traveling through passageways **22** at the powdered medicament in holding portion **20** to fluidize or assist in fluidizing the powdered medicament. Air flowing from the exit ports **26** impinges on the powdered medicament and extracts it from the holding portion **20** to mix in the air to produce a dust cloud in hold-up chamber **14**. Hold-up chamber **14** is in flow communication with and positioned immediately above holding portion **20**. Hold-up chamber **14** is configured to maintain the powdered medicament in a fluidized state during inhalation by the user, and may also assist in fluidizing the powdered medicament. Moreover, as noted at column 7, lines 22-28, "[h]old-up chamber **14** is accordingly designed to produce or assist in producing an air flow pattern such that the substance may be readily deaggregated upon inhalation by the user and maintained in a deaggregated condition during inhalation. Preferably, hold-up chamber **14** is configured to produce a swirling or cyclonic air flow in hold-up chamber **14**." As noted at column 6, lines 50-60 relied upon by the Examiner, the average velocity of the flow through the air entry passageways **22** (tubes) is equal to the volume flow rate divided by the cross-sectional flow area. The example noted in column 6, lines 50-60 is a volume flow rate of 8 L/min through the various tube configurations (having cross-sectional flow areas of from about 0.024 cm^2 to about 0.064 cm^2) that results in a flow rate (velocity) ranging from about 75 km/hr to about 210 km/hr.

The '160 patent teaches a multi-dose device (each of holding portions **20** holding a dose) that fluidizes the powder in two steps - first in the holding portion **20**, and then in the specially configured hold-up chamber **14**. In particular, the '160 patent teaches the importance of hold-up chamber **14** being configured to deaggregate the substance and to maintain the substance in a fluidized state during inhalation. *See* column 7, lines 16-26 of the '160 patent. In contrast, the '931 patent teaches a single-dose device that suspends the drug in powder form in the single dose capsule, the suspended drug exiting the capsule for inhalation by the user. Applicants respectfully submit that there is no motivation or suggestion to combine the teachings of these two patents. In particular, the flow rates through air entry passageways or tubes **22** to fluidize the substance in holding portion **20** is inapposite to fluidizing the powder contained in capsule CP disclosed in the '931 patent. The structure and mechanism for suspending the

powder in capsule CP of the '931 patent is completely different from that the structure and mechanism used to suspend the substance in holding portion **20** and hold-up chamber **14** of the '160 patent. Therefore, one skilled in the art would have no motivation to combine the teachings of these two patents. Moreover, a modification to the device disclosed in the '931 patent to include the structure of the '160 patent that provides the flow rates cited by the Examiner in would destroy the operability of the device of the '931 patent, which is designed to provide for puncturing and suspending of the drug powder through use of only the hollow needle **120**.

Moreover, there is no motivation or suggestion to use the capsule CP as taught in the '931 patent in the device disclosed in the '160 patent for at least the reason that the hold-up chamber **14** would be inoperable with a capsule instead of a powdered substance to be fluidized. This provides yet another reason why one skilled in the art would not combine the teachings of these two patents.

As the Federal Circuit has explained, "identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) (internal citations omitted). Because there is no motivation, suggestion or teaching of the desirability of combining the teachings of the '931 and '160 patents, Applicants respectfully submit such a combination is improper. Therefore, the Examiner has not established a *prima facie* case of obviousness, and the rejection of claims 14, 15, 18, and 19 cannot properly be maintained.

Priority

On page 2 of the Office Action, the Examiner requests that the current status be provided for the nonprovisional parent application 09/835,302 to which the above-captioned application claims priority. Paragraph **[0001]** has been amended herein to reflect that application number 09/835,302 is now U.S. Patent No. 6,766,799.

CONCLUSION

Prompt and favorable consideration of this Amendment is respectfully requested, All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: October 1, 2004

Respectfully submitted,

By _____

Andrea G. Reister
Registration No.: 36,253
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401
(202) 662-6000
Attorney for Applicant